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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,471	08/29/2001	Gang Liu	6724.US.P1	7987

7590

09/08/2003

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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 09/08/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/941,471

Applicant(s)

LIU ET AL.

Examiner

Taylor Victor Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 & 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The Status of Claims :

Claims 1-75 are pending.

Claims 1-75 have been rejected.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-75) in Paper No. 11 is acknowledged. Furthermore, applicants have elected one species among the claimed compounds: methyl 2-{4-[(N-acetyl-4-[(carboxycarbonyl)(2-carboxyphenyl)amino]-3-ethylphenylalanyl)amino]butoxy}-6-hydroxybenzoate in Paper No. 12.

Claims 1-9, 11, 14-19, 22, 25, 30-35, 40-44, 49, 50-52, 55-58, 61-67, and 69-75, drawn to the heterocyclic pro-drug containing various heterocycles withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to the nonelected group II, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.

DETAILED ACTION

1. The continuing data of the CIP of 09/918,928 on 7/31/2001, now pending, which is a CIP of 09/650,922 on 8/29/2000 has been entered in page 1 of the specification.

Priority

2. None.

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Drawings

3. None.

Specification

The disclosure is objected to because of the following informalities:

- the title of the example "423728 Example 30 Zhili Xin" line 16 on page 70 is recited. However, this is improper. It should be changed to "Example 30".
- the title of the example "Example 34 Zhili Xin" line 36 on page 72 is recited. However, this is improper. It should be changed to "Example 34".

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

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scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-75 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2-69 and 89-94 of copending Application No. 10/085,157.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-75 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 19-23 of copending Application No. 09/918,928. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the claimed invention of the instant invention and the claims of Application No. 09/918,928

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is the moieties of A groups ,such as heterocycloalkyl aryl, cycloalkylaryl of the currently claimed inventions, which would not overlap the claims of Application No. 09/918,928. Even so, the currently claimed inventions has the broad genus which contains the claims of Application No. 09/918,928 ; therefore, the instant claims are obvious over the claims of Application No. No. 09/918,928.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/085157. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the claimed invention of the instant invention and the claims of Application No. 10/085157 is that the limitation of Z groups in claim 1 of Application No. 10/085157 has the broad genus which contains the currently claimed invention; therefore, the instant claims are obvious over the claims of Application No. 10/085157.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

Claims 1-75 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. According to copending Applications No. 10/085157, the claims of both applications share the same currently claimed invention: for example, methyl 2-{4-[(N-acetyl-4-[(carboxycarbonyl)(2-carboxyphenyl)amino]-3-ethylphenylalanyl)amino]butoxy}-6-hydroxybenzoate. Also, the inventors are not identical with one another. For example, the inventors of the claimed invention are Gang Liu, Zhili Xin, Zhonghua Pei, Bruce G. Szczepankiewicz, David A. Janowick, and, whereas Application No. 10/085157 has two more persons, Thorsten K. Oost and Xiaofeng Li, than those of the claimed invention. Therefore, this is unclear who invented the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 703-305-0809. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Ray W. Vth
9/3/03